Rapid ART:

Rapid Initiation of Antiviral Therapy Protocol for newly diagnosed HIV positive adults

Contra Costa Health Services

Version 1.4 November 29, 2016

**Purpose:**

Currently in Contra Costa County, 30% of newly diagnosed HIV positives are not linked to care within 30 days, the time from diagnosis to initiation of antiviral therapy averages many months, and there are additional months before they achieve virologic suppression. During this time period these HIV+ individuals remain potentially at risk for spreading HIV to others via sexual contact or intravenous drug use. Eliminating the HIV epidemic in the US will require addressing this population and shortening the window of time after diagnosis in which they are at risk for transmitting HIV to others. A recent study found that among heterosexual couples, viral suppression reduced the risk of sexually transmitting the virus to an uninfected partner by 96%. Although 87% of HIV positives in Contra Costa County are aware of their HIV+ status, only 70% are on antivirals and virally suppressed. In 2014, 104 people were newly diagnosed with HIV in Contra Costa County. Rapid initiation of antiviral therapy (Rapid ART) is now recommended to be offered to newly diagnosed HIV+s as an effective means to close this gap of diagnosed but not virally suppressed individuals.Reference:http://cchealth.org/aids/pdf/HIV-surveillance-brief2016.pdf

**Background:**

San Francisco piloted a rapid initiation of antiviral therapy protocol in 2013. The goal was to reduce the time from diagnosis to initiation of ART from weeks/months to hours/days. They initially targeted new patients with acute HIV infection, and then extended the protocol in 2014 to include all new diagnoses of HIV. They were able to reduce the mean time to initiation of ART from 37 days to 1 day, and the time from diagnosis to viral load suppression from 132 days to 56 days. Patient acceptance was high, with 99% of patients offered Rapid ART still taking ART 60 days after ART initiation versus only 80% offered ART via traditional approach. They are now expanding their Rapid ART protocol to include all testing and treatment sites within the City and County of San Francisco by 2020.

**Outcome Goals of Rapid ART:**

Delivering antiviral therapy (ART) as soon as possible after diagnosis:

1. Improves morbidity and mortality in all stages of infection (START INSIGHT Team NEJM 2015).
2. In acute/recent HIV infection: limits reservoirs and hyper-infectivity (Jain et al. JID 2013; Saez-Ciron et al. VISCONTI team, PLoS Pathog. 2013)
3. Reduces transmission by 96% (HPTNO52-Cohen et al.NEJM 2011)
4. With use of currently available antiviral regimens poses a very low risk of developing antiviral resistance when ART is started while awaiting results of resistance testing and modifying therapy once resistance test results are known. (data provided by Oliver Bacon, MD, MPH, SF Dept. of Public Health)

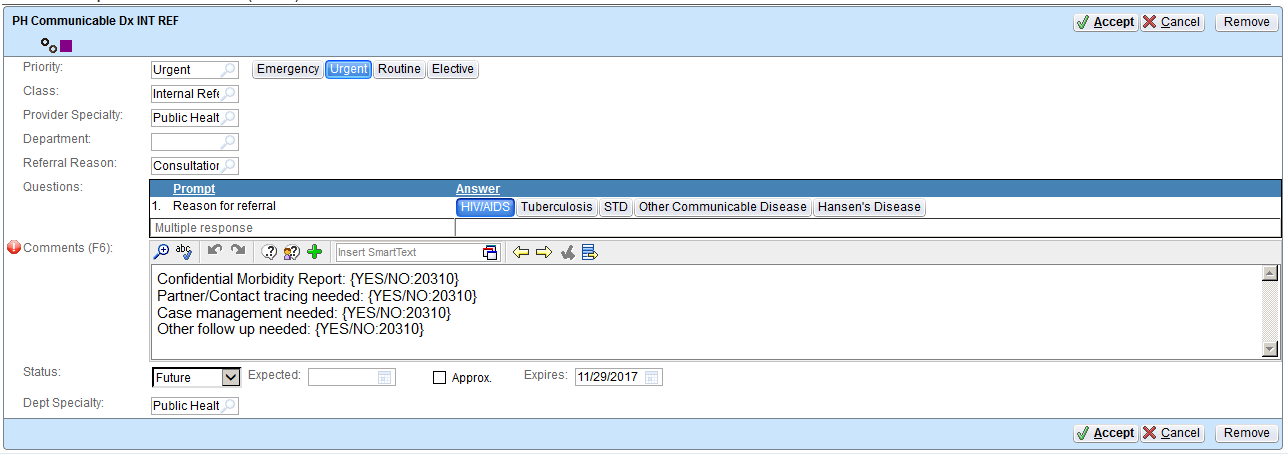
**Process Goals of Rapid ART:**

1. All newly diagnosed HIV+s navigated to Positive Health Clinic within 7 days of confirmed diagnosis.
2. Positive Health Providers start ART on the first visit
3. Hospitalized patients start ART before hospital discharge (consider consulting positive health clinic clinicians for advice on regimen selection)

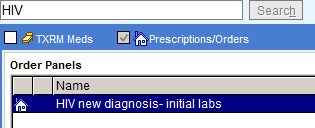
**Services that should be provided to patients upon diagnosis**:

(Provided by clinicians, social workers, case managers, and/or financial benefits counselors, etc.)

1. Disclosure of positive HIV test result
2. Counseling
3. Risk reduction for partners: safe sex ed, Pre-exposure prophylaxis (PreP) with Truvada
4. Benefits/Insurance navigation including plan for medication access
   1. Emergency ADAP (AIDS Drug Assistance Program)
   2. Presumptive Medi-Cal
5. Linkage to HIV outpatient care (Positive Health Clinic) within 7 days. Use Public Health Communicable Disease Internal Referral:



1. Medical evaluation including baseline labs (“HIV New Diagnosis Initial Labs” panel:



Includes: T cells, HIV quantitative RNA, comp panel, HLA B5701, chronic hepatitis panel, CBC/d, RPR, toxo IgG, urinalysis, microalbumin/creatinine ratio, quantiferon-TB, HIV genotype). Labs should be drawn before patient takes their first dose of ARVs. ARV initiation can begin before results are available.

1. Immediate ART start at first Positive Health Clinic visit (or in hospital if admitted)
2. Check in with patient 1-2 days after ART initiation by phone/text/email by clinician/social worker/case manager
3. Schedule follow-up in 1 week by clinician

**Who is eligible for immediate ART?**

1. Anyone with a new, confirmed HIV diagnosis unless there is a clear contraindication to starting immediate ART
2. Known HIV+s who are hospitalized and previously not engaged in care and not on ART with a clear, uncomplicated ART history that suggests a low likelihood of ART resistance (start while in hospital once stable and tolerating oral meds)

**Who is not eligible for immediate ART?**

1. Persons for whom immediate ART might be medically dangerous and who should undergo a thorough evaluation and stabilization before ART:
   1. Untreated cryptococcal meningitis (defer ART for 5 weeks after the diagnosis and antifungal treatment initiation)
   2. Pulmonary or gastrointestinal Kaposi’s sarcoma before chemotherapy (usually Doxil) has been started
   3. Active Tuberculosis (consider deferring ART for 5 weeks after the diagnosis and anti-TB treatment initiation, consult with TB program staff)

**Recommended Rapid ART regimens:**

|  |  |  |  |
| --- | --- | --- | --- |
| *Regimen* | *Pill Burden* | *Pros* | *Cons* |
| dolutegravir (Tivicay) 50mg once daily  tenofovir alafenamide 25mg/emtricitabine 200mg (Descovy) once daily | 2 pills once daily | -Rapid drop in viral load  -Well tolerated  -High barrier to resistance  -Once daily dosing | Limited experience |
| darunavir (Prezista) 800mg once daily  ritonavir (Norvir) 100mg once daily  tenofovir alafenamide 25mg/emtricitabine 200mg (Descovy) once daily | 3 pills once daily | -High barrier to resistance  -Clinical experience suggests efficacy even if M184V mutation present  -Once daily dosing | Drug interactions (ritonavir a CYP3A4 inhibitor) |
| raltegravir (Isentress) 400mg twice daily  tenofovir alafenamide 25mg/emtricitabine 200mg (Descovy) once daily | 1 pill twice daily  +  1 pill once daily | -Rapid drop in viral load  -Well tolerated | BID dosing |
| Tenofovir alafenamide 25mg/emtricitabine 200mg/ elvitegravir 150mg/cobicistat 150mg (Genvoya) once daily | 1 pill once daily | -Rapid drop in viral load  -Once daily dosing  -Lowest pill burden | Drug interactions (cobicistat a CYP3A4 inhibitor)  -possibility of Integrase inhibitor and nucleoside drug resistance with failure seen in trials |

**Anti-HIV meds to avoid until results of resistance testing, HLA-B5701 are known:**

1. Non-Nucleoside Reverse Transcriptase Inhibitors (NNRTIs): This class is most associated with transmitted drug resistance
2. Abacavir containing regimens: High risk of fatal abacavir hypersensitivity reaction if HLA-B5701+

**Resources for Clinicians:**

1. CCRMC HIV specialists:
   1. Judy Bliss 925-346-4286
   2. Larry Boly 925-346-4254
   3. Chris Farnitano 925-408-1547
   4. Jamie Pehling 925-346-4734
   5. Tony Pizzo 925-346-4102
   6. Daniel Moring-Parris 408-332-3681
2. HIV Warmline (UCSF HIV telephone consultation service) 8AM-5PM M-F: 800-933-3413